SUMMARY OF THE
ON-SITE ASSESSMENT COMMITTEE MEETING
JUNE 30, 1999

The On-site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Wednesday, June 30, 1999, at 8:30 a.m. Eastern Daylight Time (EST) as part of the Fifth NELAC Annual Meeting in Saratoga Springs, NY. In the absence of the committee chair, the meeting was led by Mr. R. Wayne Davis of the South Carolina Department of Health and Environmental Control. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to discuss items set forth in the agenda distributed prior to the meeting, most notably assessor checklists and assessor training.*

INTRODUCTION

The meeting was called to order with an introduction of committee members and a review of ground rules.

PROPOSED CHANGES TO THE NELAC STANDARDS

Mr. Davis explained that the committee's proposed changes to the standards are for the purposes of clarification and consistency. Although most of the proposed changes generated little discussion, the following items were discussed in more detail:

- **Section 3.3.2** - It was suggested that wording regarding the completion and reporting of a follow-up assessment should be revised for consistency with Chapter 4, Section 4.1.3. Participants generally agreed that a follow-up assessment should be completed within 30 days of the date on which a plan of corrective action is submitted. It was also suggested that the committee include a timeline or flow chart in this section.

- **Section 3.5.6** - A typographical error in proposed changes to this section posted on the NELAC Internet site and included in meeting packets was brought to the attention of participants. "Plan of correction action report" should have been posted as "plan of corrective action." A participant expressed dissatisfaction with this terminology because of its perceived inconsistency with Chapter 4, Section 4.1.3 and requested a return to "corrective action report." Another participant expressed great satisfaction with the terminology because of its perceived clarity and requested, instead, that Section 4.1.3 be modified to include the term "plan of corrective action."

Following discussion of proposed changes to the standards included in the participants' meeting packets, the committee opened the issue to the floor for suggestion of additional changes to the standards. Mr. Davis noted that although the committee could not guarantee that suggested changes would be effected in time for the Fifth NELAC Annual Meeting voting session, all suggestions made by participants would receive the full attention of the committee. He also encouraged the submission of written comments. The following comments and suggestions were taken under advisement:

- **Section 3.2.3** - In discussion of this section, a representative from the State of Florida expressed the desire for training as soon as possible because Florida is in the first class of accrediting authorities.

- **Section 3.4.3.b** - It was suggested that "Quality Assurance Plan" be changed to "Quality Manual" in order to maintain consistency between NELAC Standards.

- **Section 3.5.3k** - It was suggested that "initial method validation study" be changed to "demonstration of capability" in order to maintain consistency between the NELAC Standards.

- **Section 3.5.3p** - Participants representing the laboratory community suggested rewording this section to include a provision that a laboratory shall not be held liable for findings of an internal audit that have been or are being corrected and noted such a provision in Good Laboratory Practices (GLP) regulations. This suggestion generated moderate discussion. It was noted that the GLP process is largely applicable to product laboratories and includes such a provision in order to protect the laboratory in product litigation. In contrast, the NELAC process is being modeled after the International Standardization Organization (ISO) process. The committee also noted that assessors will be responsible to their accrediting authority and that it is assumed that the accrediting authority will address auditing practices.

- **Sections 3.6.1 and 3.6.4** - It was noted that the items enumerated in these sections are close to subsection elements in Chapter 5, Quality Systems, but do not include all of Chapter 5. It was suggested that the committee either make the list very consistent with all subheadings in Chapter 5 or simply reference Chapter 5.

- **Section 3.7.2** - Participants representing the laboratory community requested that comprehensive assessment reports include positive findings in addition to deficiencies. It was noted that such an inclusion would constitute a useful tool for laboratories in communicating with States that do not have comparable on-site assessment information.

- **Section 3.7.4** - Participants expressed concerns with maintaining confidentiality and suggested that assessment reports be released only to the accrediting authority. The accrediting authority could release the reports to laboratories.

- **Section 3.7.5** - Participants expressed similar concerns with maintaining confidentiality and suggested that only the accrediting authority should retain copies of assessment reports.

ON-SITE SURVEY

At the request of the committee, incoming member Ms. Marlene Moore had reviewed an on-site assessment survey included with registration materials. The survey constitutes a means for the committee to ascertain prevailing opinion concerning format and content of assessor checklists and technical training for assessors. She noted that she had received few responses and urged

attendees to return completed surveys so that the results might be informally summarized for the Fifth NELAC Annual Meeting closing plenary.

ASSESSOR CHECKLISTS

Mr. Davis introduced the topic of assessor checklists by acknowledging the presence of "carry-over errors" in the checklists posted on the NELAC Internet site and requesting that discussion center on format rather than content. He suggested that attendees submit written comments on the technical aspects of the checklists for committee review. Ms. Rosanna Buhl provided a brief overview of the evolution of the checklists and requested constructive feedback on the level of specificity required in the checklists. Mr. Charles Dyer then reported on proposed changes to the Quality Systems Assessor Checklist he had prepared on behalf of the committee. Mr. Dyer noted that he had whittled the 72-page Quality Systems checklist included in Chapter 5 of the NELAC Standards to 60 pages by eliminating duplication of questions and consolidating citations. With that, the committee opened the issue to the floor for comments and suggestions. Vigorous discussion ensued; the topic of assessor checklists proved to be a controversial topic.

It was noted that the checklists, due to format, are cumbersome to use. The flow of the checklists require that the auditor move physically from one department to another (human resources and/or quality assurance, sample handling, analytical laboratory, etc.) in an order that is not most efficient. "Bullet" items are in compound/complex sentence form and prove confusing when they are several lines long. Dr. Carl Kircher, chair of the Regulatory Coordination Committee and an employee of the Florida Department of Health, noted that Florida is a member of the first class of approved accrediting authorities. He asked permission to provide the On-site Assessment Committee with suggested reformatting of bullet items. In response, Mr. Davis noted that the committee would appreciate any effort that anyone wishes to give the checklists. Dr. Kircher commented that his State auditors will probably submit a copy of reformatted checklists to testing laboratories prior to an audit. The committee pointed out that since the purpose of assessor checklists is consistency, it will not be permissible for the state of Florida to use one version of the checklists while other states are using another version. Mr. Davis noted that this issue is an issue for the NELAC Board of Directors. Dr. Kircher asked that the committee make the board aware of this issue so that the first class of approved accrediting authorities can have an answer before they proceed.

Mr. Jerry Parr, as a representative of the Environmental Laboratory Advisory Board (ELAB), took exception with the characterization of assessor checklists as ensuring consistency. He noted that the purpose of *training* is to ensure consistency and characterized the checklists as a tool to be used by the assessors. Mr. Parr asked if the On-site Assessment Committee had received ELAB's report on assessor checklists. The committee indicated that they had already responded to the report and that their response should be available at the ELAB meeting. Mr. Davis noted that the checklists are not part of the standards: they are a part of the assessor training manual. He asked for participant input regarding whether the checklists should be made part of standards and how should they be approved by the organization.

The participants were divided as to whether the posted assessor checklists are too specific or too general. Members of the laboratory and consultant communities tended to see the technology

checklists as too specific. Members of the regulatory community tended to see the checklists as too general. In response, the committee characterized the checklists as a "moving target" and noted that there will be a transition period before environmental laboratories move to a total quality systems approach. It was noted that quality systems checklists may have to be reworded because they are subjective. As discussion of method-specific versus technology-specific checklists progressed, the committee noted that a quality systems audit verifies that a laboratory is conforming to those regulations to which they are supposed to conform. It was noted that if a specific method is mandated by the regulations, then that method-specific criteria will be included in the audit.

A participant recommended that the committee investigate an ISO standard for preparing assessor checklists, if such a standard exists. He also commented that in the absence of training, the checklists are not user-friendly. He advocated training for using assessor checklists and suggested that a video format would be invaluable. In response to his observation that the assessor needs pre-information on the laboratory, the committee noted that the accreditation application should provide the necessary information. Some weaknesses were noted in the assessor checklist for gravimetric analyses. Another issue raised by participants was the standardization of the accreditation application process. They deemed this a coordination issue that needs to be addressed by some committee. Although specific elements do have to be included in every application, applications are not alike for all states.

ASSESSOR TRAINING

The committee introduced the issue of assessor training by presenting a mission statement on technical training courses for assessors. This mission statement read as follows:

> The purpose of the technical training courses is to ensure consistency of knowledge and techniques among the NELAC assessors. The technical courses assume a level of basic knowledge of the course subject and will, therefore, concentrate on the elements of the technology or methods which are key to properly assure laboratory competency to deliver data of known and documented quality.

It was suggested that the wording of the mission statement be used to replace the wording in Section 3.2.3 that explains the purpose of technical training. An informal straw poll was conducted by a show of hands. The suggestion met with no opposition and was approved by the committee as a proposed change to the standard.

Technical training for assessors proved to be a controversial issue. It was suggested that technical training be outlined by NELAC fields of testing and that the training start with general principles and follow up with fine points of analysis. Participants representing State regulators expressed concerns that the number of training courses and depth of instruction would increase expense and burden of work for a small auditing staff. The committee noted that it was their intent to set up a system of training that was tough but fair and that they are working toward a minimum level of assessor competency. The committee also noted that they have conceptualized that all assessors will attend basic training and then will attend specific technical training as appropriate. Additional

concerns voiced by participants centered around the timeline for accreditation. They suggested that assessor training is an emergency need. It was noted that if State assessors fail training courses, then State manpower will be depleted and implementation will fail. In response, the committee noted that action dates were set by the States.

CONCLUSION

The allotted meeting time having expired, Mr. Davis thanked members of the audience for their input and adjourned the meeting.

Attachment A

ACTION ITEMS
ON-SITE ASSESSMENT COMMITTEE MEETING
JUNE 30, 1999

Item No.	Action	Date to be Completed
1.	Committee to review suggestions made at NELAC V.	NELAC Vi

Attachment B

PARTICIPANTS
ON-SITE ASSESSMENT COMMITTEE MEETING
JUNE 30, 1999

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